

CLAIMS

1. A method for producing pharmaceuticals or parts of pharmaceuticals or food supplements or parts thereof,
5 thereof,
- by coating substrates for pharmaceutical applications or substrates for applications as food supplements for humans or animals with a
10 film-forming coating agent which is mixed with at least one further substance suitable for said purposes,
- where the film-forming coating agent and the
15 further substance are initially present separate from one another as liquid, sprayable individual portions in the form of a solution or dispersion, and
- are sprayed by means of one or more spray devices which have, singly or together, at least two separate nozzles for liquids, and their spray beams overlap,
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- in such a way that the individual portions sprayed from the separate nozzles are mixed during the spraying process, the mixture impinges on the substrate and forms thereon, after evaporation of the liquid, a continuous film coating, resulting
25 in the pharmaceutical, the food supplement or the part thereof,
30
- characterized in that
- 35 the amounts of the individual portions are varied during the spraying process so that the coating agent and the further substance are present in a concentration gradient from the inside to the

outside relative to the dried film coating.

2. The method as claimed in claim 1, characterized in that the substrates for pharmaceutical applications are active ingredient crystals, active ingredient-containing cores, tablets, granules, pellets, capsules or parts of capsules.
3. The method as claimed in claim 1 or 2, characterized in that the film-forming coating agent is a cellulose derivative or a (meth)acrylate copolymer which may where appropriate comprise further pharmaceutical excipients.
4. The method as claimed in one or more of claims 1 to 3, characterized in that characterized in that the further substance is an acid, a base, a plasticizer, a release agent, a pigment, a stabilizer, an antioxidant, a further film-forming coating agent or an active pharmaceutical ingredient or a mixture thereof.
5. The method as claimed in one or more of claims 1 to 4, characterized in that a substrate which comprises an acid-sensitive active ingredient is coated with a gradient of a coating agent which is (meth)acrylate copolymer comprising anionic groups which are wholly or partly neutralized, and of a further substance which is a (meth)acrylate copolymer comprising anionic groups which is neutralized less than the first-mentioned, or not at all, where the concentration of the further substance increases from the inside to the outside.
6. The method as claimed in one or more of claims 1 to 4, characterized in that a substrate which comprises an acid-sensitive active ingredient is

coated with a gradient of a coating agent which is (meth)acrylate copolymer comprising anionic groups, and of a further substance which is a base, where the concentration of the base decreases from the inside to the outside.

7. The method as claimed in claim 5 or 6, characterized in that the acid-sensitive active ingredient is a protein, a peptide or a proton pump blocker.

8. The method as claimed in claim 7, characterized in that the active ingredient is omeprazole, esomeprazole, lanzoprazole, rabeprazole, pantoprazole.

9. The method as claimed in one or more of claims 1 to 4, characterized in that a substrate which comprises an alkali-sensitive active ingredient is coated with a gradient of a coating agent which is (meth)acrylate copolymer comprising amino groups, which is wholly or partly neutralized, and of a further substance which is a (meth)acrylate copolymer comprising amino groups, which is neutralized less than the first-mentioned, or not at all, where the concentration of the further substance increases from the inside to the outside.

10. The method as claimed in one or more of claims 1 to 4, characterized in that a substrate which comprises an alkali-sensitive active ingredient is coated with a gradient of a coating agent which is (meth)acrylate copolymer comprising amino groups, and of a further substance which is an acid, where the concentration of the acid decreases from the inside to the outside.

11. The method as claimed in claim 9 or 10,

characterized in that the alkali-sensitive active ingredient is an analgesic, antihistamine, a protein, a peptide.

- 5 12. The method as claimed in claim 11, characterized in that the active ingredient is acetylsalicylic acid, ranitidine or famotidine or salt thereof or a stereoisomer thereof.
- 10 13. The method as claimed in one or more of claims 1 to 4, characterized in that a substrate which comprises an active ingredient sensitive to a pigment is coated with a gradient of a coating agent which is a (meth)acrylate copolymer which
15 comprises no or amounts of the pigment which are only non-critical for the active ingredient, and of a further substance which is a pigment in an amount harmful for the active ingredient and may, where appropriate, in turn be mixed with a
20 (meth)acrylate copolymer, where the concentration of the pigment increases from the inside to the outside.
- 25 14. The method as claimed in claim 13, characterized in that the pigment-sensitive active ingredient is acetylsalicylic acid or ascorbic acid.
- 30 15. The method as claimed in one of more of claims 1 to 4, characterized in that a substrate is coated with a gradient of a coating agent which is (meth)acrylate copolymer and comprises 10 to 50% by weight of a plasticizer, and of a further substance which is a (meth)acrylate copolymer and comprises no or less than 10% by weight of a
35 plasticizer, where the concentration of the further substance increases from the inside to the outside.
16. The method as claimed in claim 15, characterized

in that the substrate comprises active ingredient-containing granules, pellets or active ingredient crystals.

- 5 17. The method as claimed in one or more of claims 1 to 16, characterized in that two or more two-fluid nozzles or one or more three-fluid nozzles are employed as spray device.
- 10 18. The method as claimed in one or more of claims 1 to 17, characterized in that the spray application takes place in a drum coater, a coating pan, a fluidized bed apparatus or a spray sifter.
- 15 19. The method as claimed in claim 18, characterized in that the spray application takes place by means of spray devices as fixed installation.
- 20 20. A pharmaceutical or part of a pharmaceutical, food supplement or part thereof, which can be produced by a method as claimed in one or more of claims 1 to 19.
- 25 21. A drum coater, coating pan, fluidized bed apparatus or spray sifter suitable for carrying out a method as claimed in one or more of claims 1 to 19, comprising one or more three-fluid nozzles as spray device.
- 30 22. The use of one or more spray devices for carrying out a method as claimed in one or more of claims 1 to 19.